PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : **A61L 2/00**	**A2**	**(11) International Publication Number:**	**WO 99/32159**
		(43) International Publication Date:	1 July 1999 (01.07.99)

(21) International Application Number: PCT/US98/27503

(22) International Filing Date: 22 December 1998 (22.12.98)

(30) Priority Data:
9727533.3 22 December 1997 (22.12.97) GB

(71) Applicant *(for all designated States except US)*: MINNESOTA MINING AND MANUFACTURING COMPANY [US/US]; 3M Center, P.O. Box 33427, Saint Paul, MN 55133–3427 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: SCHULZE, Gerhard, F., W. [DE/DE]; Am Morjansbusch 51 A, D–41239 Moenchengladbach (DE). KUEPPER, Anton [DE/DE]; Jupiter Str. 13, D–41564 Kaarst (DE). KAPS, Wolfgang [DE/DE]; Lange Hecke 87, D–41564 Kaarst (DE). FETTWEISS, Wolfgang, L. [DE/DE]; Rudolf–Breitscheid–Strasse 16, D–40595 Düsseldorf (DE).

(74) Agents: HOHENSHELL, Jeffrey, J. et al.; Minnesota Mining and Manufacturing Company, Office of Intellectual Property Counsel, P.O. Box 33427, Saint Paul, MN 55133–3427 (US).

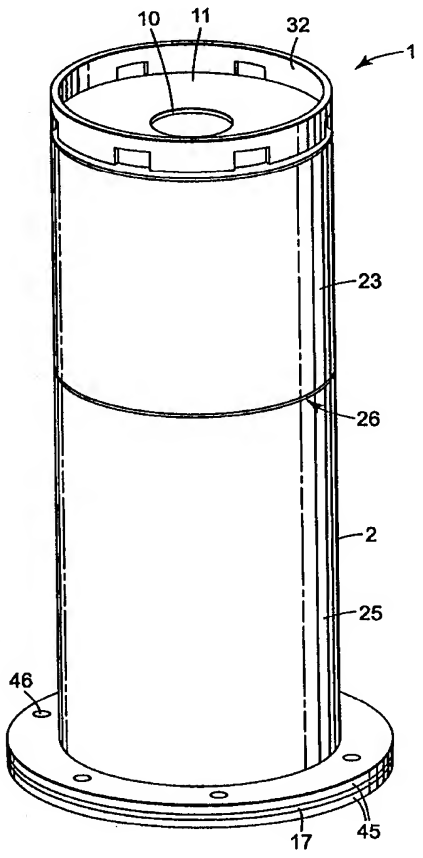
(81) Designated States: AU, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: HOUSING FOR A STERILIZATION MONITORING DEVICE

(57) Abstract

A self–contained sterilization monitoring device, for use in a sterilization chamber for monitoring a sterilization cycle, has a sterilant challenge load (3) and electronic means (7, 8) electrically–connected to the challenge load for determining whether or not sterilant has penetrated the challenge load adequately during a sterilization cycle. A welded, sterilant–resistant outer casing (2) provides respective compartments (20, 21) for containing the sterilant challenge load and the electronic means, the compartment (20) for the electronic means being at a reduced pressure to protect the electronic means from the temperature conditions outside the outer casing. A window (10), which is a press–fit in the casing (2), allows the transmission of data in the form of optical radiation signals to/from the electronic means in the compartment (20).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

HOUSING FOR A STERILIZATION MONITORING DEVICE

The present invention relates to electronic sterilization monitoring devices (more especially, devices which in use are exposed to the sterilization cycles that are being monitored) and is particularly concerned with the housing of such a device, and the manner in which the housing is constructed.

One example of an electronic sterilization monitoring device is described in US-A-5 565 634. The device is in the form of a sealed and self-contained test pack which, in use, is located within a sterilization chamber for the duration of a sterilization cycle and, at the end of the cycle, indicates whether or not the cycle has been effective. The test pack also records data relating to environmental conditions within the sterilization chamber with the intention that the data should subsequently be transferred to outside hardware for analysis and/or documentation. The transfer of data is preferably accomplished using infrared radiation which is transmitted through the housing of the test pack, thereby avoiding the need to be able to connect the test pack to external wiring.

The environmental conditions to which a monitoring device of that type is subjected during use (i.e., the conditions encountered in a sterilization chamber) including comparatively high temperatures and comparatively low pressures in the presence of a sterilant (e.g., steam), and the housing of the monitoring device should be capable of withstanding those conditions and of providing an appropriate environment for components within the housing without making the devices difficult to handle. It is also desirable that the housing should permit the transfer of data from within the housing without the need for a connection to external wiring.

The present invention provides a self-contained sterilization monitoring device for use in a sterilization chamber for monitoring a sterilization cycle, the device comprising: a sterilant challenge load comprising a sterilant challenge path and a sterilant sensor positioned to determine the presence of a sterilant at a predetermined location along the challenge path; electronic means electrically-connected to the sensor and operable to determine whether or not sterilant has penetrated adequately to the said predetermined location; and a sterilant-resistant outer casing which contains both the sterilant challenge load and the electronic means and provides an access opening for the entry of sterilant to the sterilant challenging path; wherein the sterilant challenge load and the electronic means are located within respective compartments within the outer casing, the compartment for the electronic means being at a reduced pressure to protect the electronic means from the temperature conditions outside the outer casing.

The present invention also provides a method of assembling a self-contained sterilization monitoring device for use in a sterilization chamber for monitoring a sterilization cycle, the method comprising the steps of: providing a sterilant challenge load comprising a sterilant challenge path and a sterilant sensor positioned to determine the presence of sterilant at a predetermined location along the challenge path; providing electronic means to be electrically-connected to the sensor to determine whether or not sterilant has penetrated adequately to the said predetermined location; assembling a first cylindrical housing for containing the electronic means and a second cylindrical housing for containing the challenge load; joining the two cylindrical housings together end-to-end with, between them, a separation plate through which are passed electrical leads for connecting the sterilant sensor to the electronic means; and withdrawing air from the first housing to reduce the pressure therein an thereby protect the electronic means from the temperature conditions outside the housing.

In accordance with another aspect of the invention, there is provided a self-contained sterilization monitoring device for use in a sterilization chamber for monitoring a sterilization cycle, the device comprising: a sterilant challenge load comprising a sterilant challenge path and a sterilant sensor positioned to determiner the presence of sterilant at a predetermined location along the challenge path; electronic means electrically-connected to the sensor and operable to determine whether or not sterilant has penetrated adequately to the said predetermined location; and a sterilant-resistant outer casing which contains both the sterilant challenge load and the electronic means and provides an access opening for the entry of sterilant to the sterilant challenge path; wherein the electronic means are located in a compartment, within the outer casing, which is at a reduced pressure to protect the electronic means from the temperature conditions outside the outer casing, and wherein the outer casing include a window for the transmission of data in the form of optical radiation signals to/from the electronic means; the window being formed from a glass material and being a press-fit in the outer casing.

The present invention further provides an electronic device having a sealed housing formed with a window through which data in the form of optical radiation signals can be transmitted, wherein the housing comprises a stainless steel material and the window is formed from a glass material and is a press-fit in the stainless steel material. In an embodiment of the invention, the window is contained in a frame of stainless steel, which is joined into the housing by a welded seam.

By way of example only, a sterilization monitoring device constructed in accordance with the invention will be described with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view of an electronic sterilization monitoring device in accordance with the invention;

FIG. 2 shows the device of Fig. 1, provided with a protective framework;

FIG. 3 is a longitudinal cross-section of the device, when provided with the protective framework as shown in Fig. 2;

FIG. 4 is an exploded view of the device shown in Fig. 1;

FIG. 5 is a plan view of a transmission plate forming part of the device of Fig. 1;

FIG. 6 is a cross-section on the line VI-VI of Fig. 5;

FIG. 7 is a plan view of a separation plate forming part of the device of Fig. 1;

FIG. 8 is a cross-section on the line VIII-VIII of Fig. 7;

FIG. 9 is a diagrammatic cross-section illustrating the join between the separation plate of Figs. 7 and 8 and adjacent components of the casing of the device of Fig. 1;

FIG. 10 shows a component of the plate of Figs. 7 and 8;

FIG. 11 is a plan view of the direction XI of Fig. 10;

FIG. 12 is a longitudinal cross-section of the component of Figs. 10 and 11; and

FIG. 13 is a perspective view, similar to Fig. 1, of an alternative form of monitoring device.

The device 1 shown in Fig. 1 is an electronic test pack for use in determining the efficacy of a sterilization cycle in the sterilization chamber of a porous-load sterilizer. The test pack is intended to be placed inside the sterilization chamber and to remain there throughout a sterilization cycle, during which time it monitors and records certain parameters to enable a determination to be made, at the end of the cycle, as to whether or not the cycle was effective. More particularly, the test pack functions to detect the presence of air or non-condensable gases in the sterilization chamber during a sterilization cycle, which air/gases might form pockets within the load that is being sterilized and prevent the effective penetration of sterilant. The presence of air could, for example, be due to an inadequate air removal phase during the sterilization cycle or to a leak in the sterilization chamber while non-condensable gases (which, in this context, means gases having a boiling point below that of the sterilant) could be carried into the chamber with the sterilant itself. To enable the presence of pockets of air/non-condensable gases to be detected, the test pack 1 includes a challenge load (described in a more detail below) which is so constructed that sterilant will be unable to reach a selected location within the load if the amount of residual air/gases in the load is too high. By detecting the presence, or absence, of sterilant at that selected location during a sterilization cycle, the efficacy of the sterilization cycle itself can be determined. The test pack has a cylindrical housing 2 within which are contained the components, including the challenge load an electronic components, necessary for the functioning of the device.

The test pack 1 may be provided with a protective framework 13, as shown in Fig. 2, which not only protects the test pack against impacts but also facilitates the handling of the test pack during use.

Figs. 3 and 4 are, respectively, a cross-section and an exploded view of the test pack, enabling the construction of the test pack (described in greater detail below) and the components that it contains to be seen. The protective framework 13 of Fig. 2 is included in Fig. 3 but omitted from Fig. 4. The challenge load is indicated by the reference numeral 3 and is designed to challenge the penetration of sterilant through an opening 4 (not visible in Figs. 1, 2 and 4) in the lower end of the housing 2 to a particular location within the housing. A first temperature sensor 5 (the electrical leads 5a of which are visible in Fig. 4) is provided within the challenge load 3 to indicate the presence/absence of sterilant location, and a second temperature sensor 6 (not visible in the drawings) is located within the housing 2 but outside the challenge load to measure the ambient temperature in the sterilization chamber. The electrical leads 6a of that second sensor are also visible in Fig. 4. The leads 5a, 6a are connected to an electronic memory 7 which records the information from the temperature sensors and provides information to a microprocessor 8 for determining if a particular sterilization cycle has been effective. A visual signal giving the results of that determination (i.e., a pass/fail decision) is provided at the end of the sterilization cycle by a pair of LEDs 9 located at the upper end of the test pack. Those LEDs 9, together with a second pair which indicates the operational status of the test pack, are visible through a window 10 (described in greater detail below) in the upper end face 11 of the housing 2. In addition, when the test pack 1 has been removed from the sterilization chamber, recorded information about a sterilization cycle may be transferred from the test pack to outside hardware for further analysis and/or documentation. The information is transferred in the form of pulses of infrared radiation generated by an infrared LED 12 within the test pack and also transmitted through the window 10. Also provided in this part of the test pack is an infrared receiver 12A enabling certain functions of the test pack to be initiated by infrared signals transmitted through the window 10 from outside the test pack.

The challenge load 3 of the test pack 1 is of the type shown in Fig. 10 of WO97/12637, to which reference may be made for more details concerning the construction of this component. For the purposes of the present description, it is noted that the challenge load 3 comprises a tube 14 (Fig. 3) which is closed at one end 15 and open at the other end where it is in communication with the sterilant opening 4 formed in an end plate 17 in the lower end of the housing 21. The tube 14 is formed from thermally-insulating material and is surrounded by a plurality of thermally-conductive blocks 18 located side-by-side, with air spaces between them, along the length of the tube. The tube

14 and the blocks 18 are carried by the end plate 17 which is formed from aluminum or a plastic material. The blocks 18 are surrounded in turn by a cylinder 19 of thermally-insulating material, for example an open cell foam, which is also carried by the end plate 17. The radial dimensions of the cylinder 19 and the surrounding housing 2 of the test pack are chosen to ensure the existence of an air space 40 (Fig. 3) around the cylinder 19, in which bags of desiccant material (not shown) are located to prevent moisture collecting around the challenge load 3 and, in particular, in the air spaces between the thermally-conductive blocks 18. The desiccant material can be any suitable material capable of functioning effectively inside the test pack 1 throughout its intended life, one suitable desiccant being the molecular sieve material available, under the trade designation "Molsieb 4A Baylith TE144", from Bayer AG of Leverkusen, Germany. The bags may be formed from a fleece material and linked together in a chain (available as a desiccative pack from Tropack of Lahnau-Waldgrimes, Germany) which is wrapped around the cylinder 19.

The construction of the cylindrical housing 2 of the test pack 1 will now be described in greater detail. It will be understood that the housing should be capable of withstanding the environmental conditions prevailing in the sterilization chamber of a sterilizer, more especially particular levels of temperature and pressure and the presence of sterilant. The housing 2 is additionally required to ensure that the electronic components 7, 8, 9, 12, are not exposed to undesirably high temperatures which may affect their reliability.

The housing 2, as can be seen from Fig. 3, is constructed to provide two separate cylindrical chamber s20, 21 disposed end-to-end within the test pack. The chamber 20, in the upper part of the test pack 1, houses the electronic components (i.e., the memory 7, microprocessor 8 and diodes 9, 12) and also the power supply 22 for those components. During assembly of the test pack, a partial vacuum is established inside the chamber 20 as will be described below to provide a degree of thermal protection for electronic components which it contains. The chamber 21, in the lower part of the test pack, houses the challenge load 3 and the associated temperature sensors. The upper chamber 20 comprises a cylinder 23, forming the chamber wall and closed at its upper end by an end plat 24 (also shown in Figs. 5 and 6) which contains the window 10 and forms the end face 11 of the housing. The lower chamber 21 comprises a cylinder 25, forming the chamber wall and closed at its lower end by the end plate 17 which carries the tube 14, the thermally-conductive blocks 18 and the thermally insulating cylinder 19 of the challenge load 3. The end plate 17 is held between two rings 45, 46 at the lower end of the test pack 1, one ring being welded to the lower end of the cylinder 25 and the other being secured by

screws 47 (only one of which is shown in Fig. 4). The second ring 46 is formed from stainless steel and protects the end plate 17.

The chambers 20, 21 are separated by a circular plate 26 (also shown in Figs 7 and 8), through which a plurality of electrical leads 27 pass, connecting the temperature sensors of the challenge load 3 in the lower chamber with the electronic memory 7 in the upper chamber. The leads 27, which are not visible in Fig. 3, are sealed in conventional glass wire ducts in apertures 28 in the plate 26. An additional, slightly larger, aperture 50 in the plate 26 is used to remove air from the chamber 20 when the housing 2 is being assembled as will be described below. The cylinders 23, 25 (including the ring 45), the lower end plate 17, the upper end plate 24 (excluding the window 10), and the separation plate 26 are all formed of stainless steel and are welded together, as will be described below.

The window 10 in the end plate 24 must be capable of transmitting optical radiation signals from the diodes 9, 12, etc., and must also be a vacuum-tight fit in the end plate 24 in order to preserve the partial vacuum within the upper chamber 20 of the test pack 1. The window 10 must also, of course, be capable of maintaining its transparency and vacuum-tight fit in the end plate 24 throughout a comparatively large number o sterilization cycles. A preferred material for the window 10 is glass, for example that available, under the trade designation "AR 8350" from Jenaer Glaswerke Schott & Gen., of Mainz, Germany. A method of fitting the window 10 into the end plate 24 will also be described below.

Inside the upper chamber 20, as already mentioned, the electronic components 7, 8, 9, 12 are protected against heat by the existence of a partial vacuum within the chamber. Additional protection is provided by a casing comprising a cylinder 29 of thermally-insulating material and two end caps 30, 31 of the same material and by the provision of an aluminum heat capacity 48 within the casing. To accommodate the electrical leads 27, the diameters of the lower end cap 31 and the cylinder 29 are such that they locate, respectively, inside and around the outside of the leads. Preferably, the thermally-insulating material has a thermal conductivity lower than that of air (suitable materials being available, for example, under the trade designation "WDS" from Wacker Chemie GmbH of Munich, Germany and, under the trade designation "Super G" from Michrotherm Europa of Sint-Niklaas, Belgium). In theory, the thermally-insulating casing 29, 30, 31 could be omitted if a complete, rather than a partial vacuum, were to be established inside the chamber 20. In practice, however, it is found that the electronic components within the chamber de-gas to some extent when the test pack 1 is in use, making the provision of a thermally-insulating casing essential since a complete vacuum cannot be maintained with any certainty. As a further (but more expensive) alternative, the electronic components

used in the chamber 20 could be selected from those capable of withstanding the elevated temperatures encountered in a sterilization chamber (typically 134°C), in which case all of the thermal protection provided for these components could be omitted.

Mounted on the tope of the upper end plate 24 of the test pack, inside an upstanding ring 32 which provides mounting points for the protective framework 13 (Fig. 2), is an actuation switch for the test pack. The switch, which has been omitted from Figs. 1 and 2, comprises a rotatably-mounted arm 33, incorporating magnets 34 which, when the arm is rotated, cause actuation of a reed relay 35 to activate the test pack 1.

A test pack 1 of the same general type to that shown in Figs 1 to 4 is described in WO 95/32742, to which reference may be made for information regarding the general principles of the operation of the test pack. Briefly, operation of the test pack 1 can be summarized as follows:

The thermal properties of the challenge load 3 are such that, when the test pack 1 is exposed to the air removal phase of a sterilization cycle, an air pocket will tend to remain at the closed end 15 of the tube 14. Similarly, non-condensable gases carried by the steam will also tend to remain at the closed end of the tube. The size of the air/gas pocket is indicative of the efficiency of the sterilization cycle, being larger when the air removal phase of the cycle is less adequate. The air/gas pocket prevents the first temperature sensor 5 from being exposed to the full effects of sterilant, thus giving rise to a difference between the temperature at the sensor 5 and the temperature at the second sensor 6.

As temperature sensors 5 and 6 measure temperatures, the temperature readings are stored in the test pack memory 7 together with time data from the microprocessor 8. Once the microprocessor 8 determines that a sterilization cycle is complete, it then determines (from the stored temperature readings) whether the sterilization cycle is satisfactory, in other words, that the sterilant has adequately penetrated the length of the tube 14 in the challenge load. More particularly, the microprocessor 8 determines if the temperature difference between the sensors 5, 6 exceeds a predetermined value at a predetermined point within the sterilization cycle and, if so, the cycle is judged to be unsatisfactory. This predetermined temperature difference is determined by validation experiments in which the performance of the electronic test pack is compared with that of a standard Bowie-Dick textile test pack according to recognized International European or National standards. For example, the test pack could be pre-programmed so that, if the temperature difference is greater than 2°C in a 2 minute and 40 second period after the chamber temperature (measured by sensor 6) reaches a sterilization hold temperature of 134°C, the cycle is considered unsatisfactory. Further, the chamber temperature (measured by sensor 6) must remain above an adequate sterilization temperature for sterilization to occur.

If the microprocessor determines that the sterilization cycle was satisfactory, one of the LEDs 9 emits a green light. If the microprocessor determines that the sterilization cycle has failed, the other LED 9 emit a red light.

While the examination of the temperature difference between the external and internal temperature (as measured by the sensors 5, 6) provides direct information on the penetration of heat to the sensor 5 located within the challenge load 3, it does not directly reflect penetration of sterilant to the sensor. By inference, rapid equilibrium between the sensing point within the challenge device and the sterilization chamber indicates the absence of an insulating air/gas pocket. In the case of a steam sterilizer, it is possible, however, to measure directly the moisture penetration to the sensing point within the challenge device. To that end, a moisture sensor, such as a conductivity sensor or a relative humidity sensor, can be used instead of or in addition to, the temperature sensor 5 to determine adequate moisture penetration to the sensing point within the challenge load and therefore, by inference, steam. The temperature sensor 6 measuring the sterilization chamber temperature remains the same.

When the test pack 1 has been removed from the sterilizer at the end of a sterilization cycle, it is desirable to transfer the data stored in the memory 8 of the unit to an outside processor or memory or a printer. As already mentioned, data is transferred in the form of pulses of infrared radiation generated by LED 12 and transmitted through the window 10 in the end face 11 of the test pack 1. Data transfer may be initiated by actuating the reed relay 35. The assembly of the end plate 24 of the test pack casing 2 and the test pack as a whole will now be described.

Assembly of the End Plate 24

Methods of fitting observation windows into gas- and pressure-tight chambers are known (see, for example, US-A-4 961 628). However, although any suitable method may be employed to fit the window 10 into the end plate 24 of the test pack 1, a preferred method is as follows:

An end plate 24 having a thickness of about 5 mm and a diameter of about 80 mm is formed from a stainless steel material having the required characteristics (chemical stability, weldability, compatibility with the window glass, and non-magnetic properties to avoid interference with the actuation switch of the test pack (see below)). Preferred stainless steel material are those of 1.4301 and 1.4571 quality. A central hole 55 having a diameter of about 25 mm is formed in the plate to receive the glass window 10. The plate is placed on a graphite carrier and a circular tablet of a suitable glass, of similar thickness to the plate 24 but having a diameter slightly less than that of the central hole 55, is pressed into the hole. The assembly is then heated up gradually to a temperature

exceeding the softening point of the glass and the glass is allowed to deform until it contacts the sides of the hold 55 in the plate 24. The temperature is then reduced even more gradually (typically over a period of about 2 hours) and, as soon as it falls once again below the softening point of the glass, the steel plate shrinks onto the glass and contains it so that, when the assembly has cooled, the glass (now slightly thicker than the plate) is secured in position by the radial pressure of the plate. Effectively, the glass window 10 is a press-fit in the stainless steel plate 24. The surfaces of the plate and window are then finished (by fire polishing on the side that will be on the inside of the casing 2, and by grinding and polishing on the other face) so that the window 10 will transmit light without undue scattering and/or diffraction. Window-containing plates of that type are available from Herberts Industrieglas GmbH & Co. of Wuppertal, Germany.

It is important, for the quality of the completed end plate 24, that the sides of the hole 55 should be free of grease, and also that they should be flat to reduce the risk of surface cracks in the glass window. To prevent corrosion, the thermal treatment should be carried out in a protective atmosphere, for example a mixture of hydrogen and nitrogen. It is also desirable to prevent carbon entering the stainless steel from the graphite carrier on which the assembly is located, while the thermal treatment is in progress, since that can affect the weldability of the material. That can be achieved, at least in the margin of the plate (where weldability is critical) by using a carrier which has a diameter slightly less (by about 5 to 10 mm) than that of the plate so that the margin of the latter is not in contact with the carrier when the thermal treatment is in progress.

Assembly of the Test Pack 1

The test pack 1 is assembled by first assembling the electronic components 7, 8, 9, 12, 22 and electrically-connecting them together inside the thermally-insulating casing 29, 30, 31. The electronic components are also connected to the leads 27 on the upper side of the separating plate 26. The cylinders 23, 25 are then located against opposite sides of the separation plate 26; the end plates 24, 17 and the rings 32, 45 are placed in position; and the assembly is clamped together in any suitable manner allowing it to be rotated adjacent the welding head of a laser welder. The latter is then operated to close each of the junctions in the test pack casing (i.e., between the components 17, 23, 26, 25, 24, 32 and 45) by a continuous welded seam formed from a series of welded spots. The seams may be formed simultaneously or consecutively.

To aid the location of the components of the test pack one against another, the cylinders 23, 25 may be formed with an external machined recesses 36 at the ends adjacent the separation plate 26, as shown in Fig. 9. Because the recesses 36 are machined, they can be matched precisely to the diameter of the plate 26.

As mentioned above, there is a partial vacuum inside the upper chamber 20 of the test pack. The vacuum is established at this stage by removing air from the chamber 20 through the aperture 50 in the separation plate 26. Prior to the removal of the air, a sealing screw 51 (shown also in Figs. 10 to 12) is located in the aperture 50 and screwed partly, but not completely, into position. The sealing screw 51 has the form of a conventional screw but is provided, additionally, with a clamping ring 52 on the underside of the head 53. The clamping ring 52 has a height of about 0.3 mm and is tooth-shaped in cross-section (as shown in Fig. 12) so that. when the screw is tightened down in the aperture 50 following the removal of air from the chamber 20, the ring 52 will cut into the surface of the plate 26 and thereby seal the chamber 20 and maintain the partial vacuum therein. Sealing screws of the type shown in Figs. 10 to 12 are known and described, for example, in GB-A-1 155 799 and DE-A-28 45 072.

The challenge load 3 is then inserted into the cylinder 25 through the lower (open) end thereof, and the ring 46 is screwed in place to complete the assembly.

If desired, a protective sleeve of plastics material (not shown in the drawings) can then be located around the completed casing 2.

Due to manufacturing constraints, it may not be possible for the various components 17, 23, 24, 25, 26 and 45 of the test pack casing to be formed from the same type of stainless steel. Where more than one type of stainless steel is used, the various materials should be compatible with regard to weldability, chemical stability and thermal characteristics. Examples of suitable stainless steels are the 1.4301 and 1.4571 quality steels mentioned above. A CO_2 pulsed laser may be used to form the welded seas between the components and, to prevent any oxidation of the stainless steel. welding should be carried out in a protective atmosphere. for example argon.

The test pack casing 2 described above provides a housing which meets the requirements of both the challenge load 3 and the associated electronic components 7, 8, 9, 12 and lends itself to a comparatively simple and cost-effective assembly method. As an alternative, however, a construction can e used in which sealing rings, rather than welded joints are employed between the various components of the casing, provided that a suitable clamping arrangement can be provided to hold the components together while preserving the self-contained nature of the test pack.

Fig. 13. for example. shows a test pack similar to that of Fig. 1 in which the end plates of the tubular casing 60 are sealed against the casing by O-rings (not visible). In Fig. 13. only the upper end plate 61. containing the data transmission window 62 can be seen. The end plates are located in respective end rings 63 which also function to hold the end plates against the end of the tubular casing 60. To that end. the plurality of spokes 64 extend under tension between the end rings and are fastened. at each end. in apertures 65

in the end rings. The spokes 64, which are preferably formed of stainless steel, are of the type commonly used in bicycle wheels and can be fastened at each end in a similar manner to provide a required retaining force on the end rings 63. The spokes 64, in addition to providing the force required to seal the end plates of the test pack housing, can also function as a framework by which the test pack can be handled.

The tubular casing 60 of Fig. 13 is shown as being formed in two parts, like the casing 2 of the test pack 1 of Fig. 1. It could, however, be a single tubular part divided internally into two compartments containing, respectively, the challenge load and the electronic components of the test pack.

In each of the test packs described above, the construction of the challenge load in the lower chamber of the housing can be modified, if required, as can the type and number of the electronic components contained in the upper chamber.

CLAIMS:

1. A self-contained sterilization monitoring device for use in a sterilization chamber for monitoring a sterilization cycle, the device comprising:

a sterilant challenge load comprising a sterilant challenge path and a sterilant sensor positioned to determine the presence of sterilant at a predetermined location along the challenge path;

electronic means electrically-connected to the sensor and operable to determine whether or not sterilant has penetrated adequately to the said predetermined location; and

a sterilant-resistant outer casing which contains both the sterilant challenge load and the electronic means and provides an access opening for the entry of sterilant to the sterilant challenge path;

wherein the sterilant challenge load and the electronic means are located within respective compartments within the outer casing, the compartment for the electronic means being at a reduced pressure to protect the electronic means from the temperature conditions outside the outer casing.

2. A device as claimed in claim 1, wherein the outer casing is a welded stainless steel casing

3. A device as claimed in claim 1 or claim 2, in which the outer casing includes a window for the transmission of data in the form of optical radiation signals to/from the electronic means.

4. A device as claimed in claim 3, when appended to claim 2, in which the window is formed from a glass material and is a press-fit in the outer casing.

5. A device as claimed in any one of the preceding claims, in which the outer casing is in the form of a cylinder and includes a transverse separation plate which divides the cylinder internally into two chambers containing, respectively, the challenge load and the electronic means.

6. A device as claimed in claim 5, when appended to claim 4, in which the window is formed in an end face of the cylindrical outer casing.

7. A device as claimed in claim 5 or claim 6, in which the outer casing comprises two cylindrical casing members placed end-to-end with the separation plate between them.

8. A device as claimed in any one of claims 5 to 7, in which electrical leads connecting the sterilant sensor to the electronic means pass through, and are sealed into, the separation plate.

9. A device as claimed in any one of claims 5 to 8, in which the reduced pressure in the compartment for the electronic means is formed by withdrawing air from the compartment through an aperture in the separation plate, which is subsequently sealed.

10. A device as claimed in any one of the preceding claims, in which the compartment for the electronic means includes a thermally-insulating material to provide additional protection for the electronic means from the temperature conditions outside the outer casing.

11. A method of assembling a device as claimed in claim , comprising the steps of laser welding the junctions between the cylindrical casing members and the separation plate.

12. A method as claimed in claim 11, further including the step of applying end plates to the outer ends of the cylindrical casing members, and laser welding the junctions between each cylindrical casing members and the respective end plate.

13. A method of assembling a self-contained sterilization monitoring device for use in a sterilization chamber for monitoring a sterilization cycle, the method comprising the steps of:

providing a sterilant challenge load comprising a sterilant challenge path and a sterilant sensor positioned to determine the presence of sterilant at a predetermined location along the challenge path;

providing electronic means to be electrically-connected to the sensor to determine whether or not sterilant has penetrated adequately to the said predetermined location;

assembling a first cylindrical housing for containing the electronic means and a second cylindrical housing for containing the challenge load;

joining the two cylindrical housings together end-to-end with, between them, a separation plate through which are passed electrical leads for connecting the sterilant sensor to the electronic means; and

withdrawing air from the first housing to reduce the pressure therein and thereby protect the electronic means from the temperature conditions outside the housing.

14. A method as claimed in claim 13, in which each of the cylindrical housings is laser welded to the separation plate.

15. A method as claimed in claim 14, further including the step of laser welding an end plate to the outer end of the first cylindrical housing, the end plate including a window for the transmission of data in the form of optical radiation signals to/from the electronic means.

16. A self-contained sterilization monitoring device for use in a sterilization chamber for monitoring a sterilization cycle, the device comprising:

a sterilant challenge load comprising a sterilant challenge path and a sterilant sensor positioned to determiner the presence of sterilant at a predetermined location along the challenge path;

electronic means electrically-connected to the sensor and operable to determine whether or not sterilant has penetrated adequately to the said predetermined location; and

a sterilant-resistant outer casing which contains both the sterilant challenge load and the electronic means and provides an access opening for the entry of sterilant to the sterilant challenge path;

wherein the electronic means are located in a compartment, within the outer casing, which is at a reduced pressure to protect the electronic means from the temperature conditions outside the outer casing, and wherein the outer casing includes a window for the transmission of data in the form of optical radiation signals to/from the electronic means; the window being formed from a glass material and being a press-fit in the outer casing.

17. A device as claimed in claim 16, in which the outer casing is formed from stainless steel.

18. A device as claimed in claim 17, in which the outer casing is a welded construction.

19. A device as claimed in any one of claims 16 to 18, in which the window is contained in a frame of stainless steel, which is joined into the outer casing by a welded seam.

5

20. A device as claimed in claim 19, in which the window is circular and is contained in a stainless steel ring.

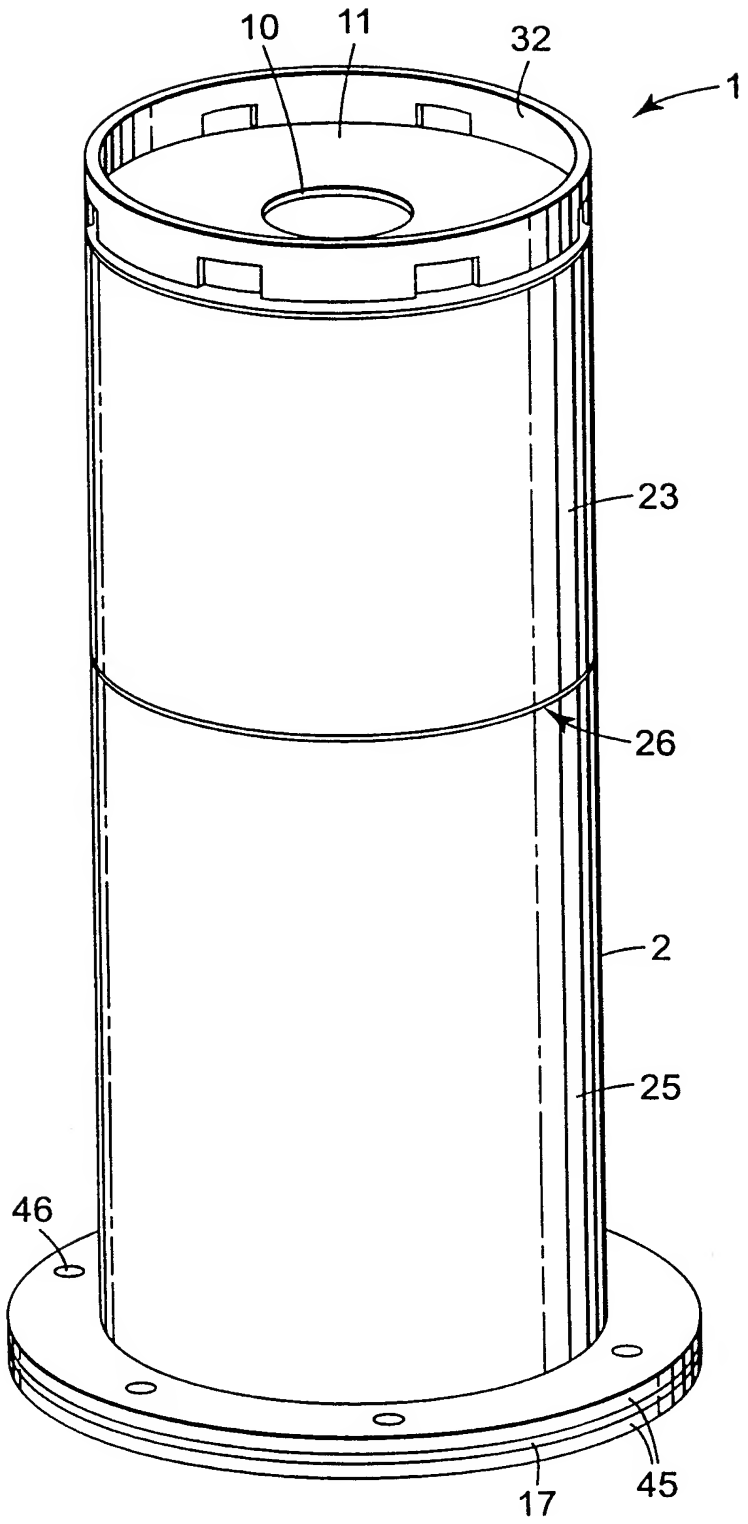


Fig. 1

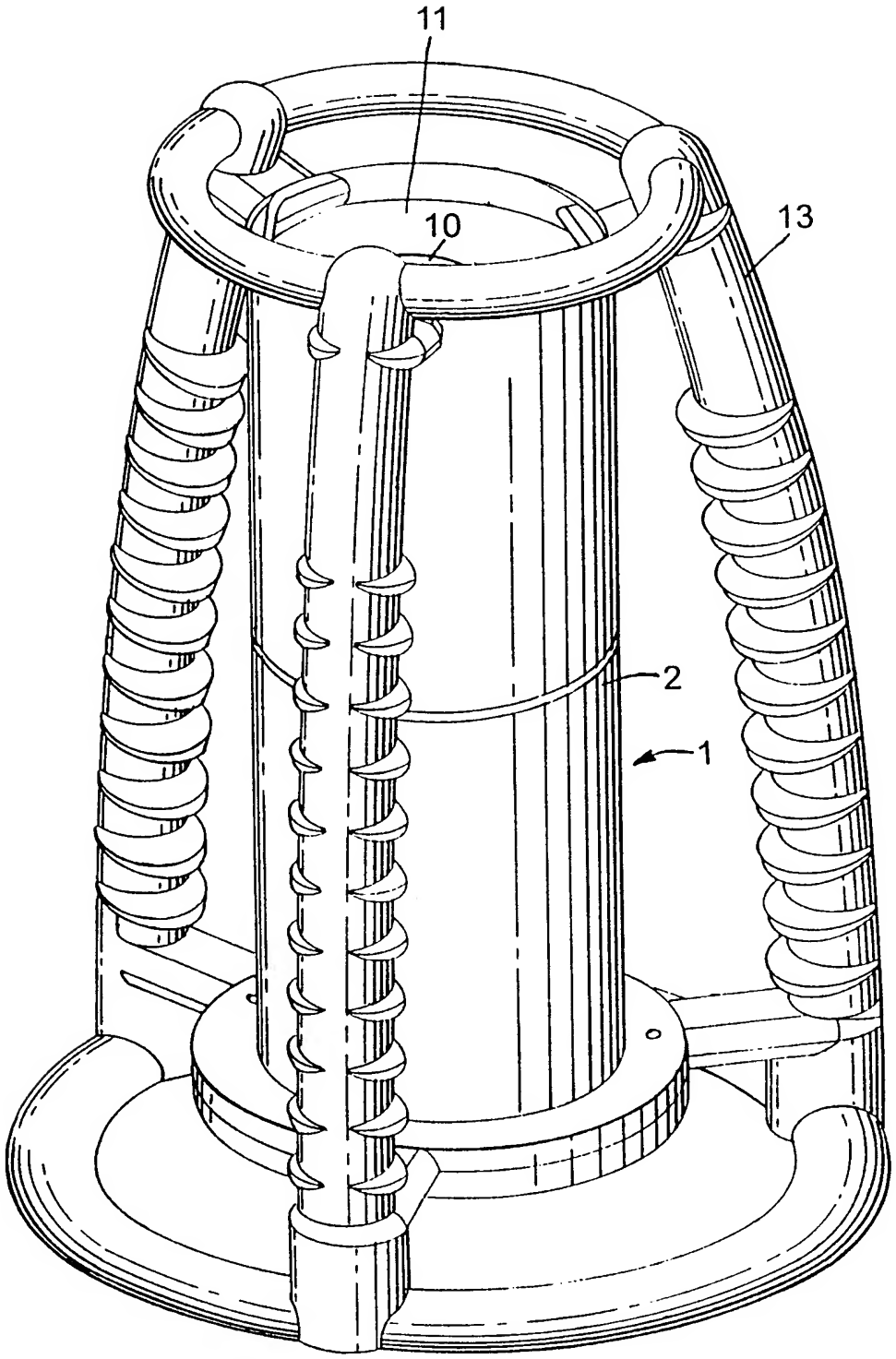


Fig. 2

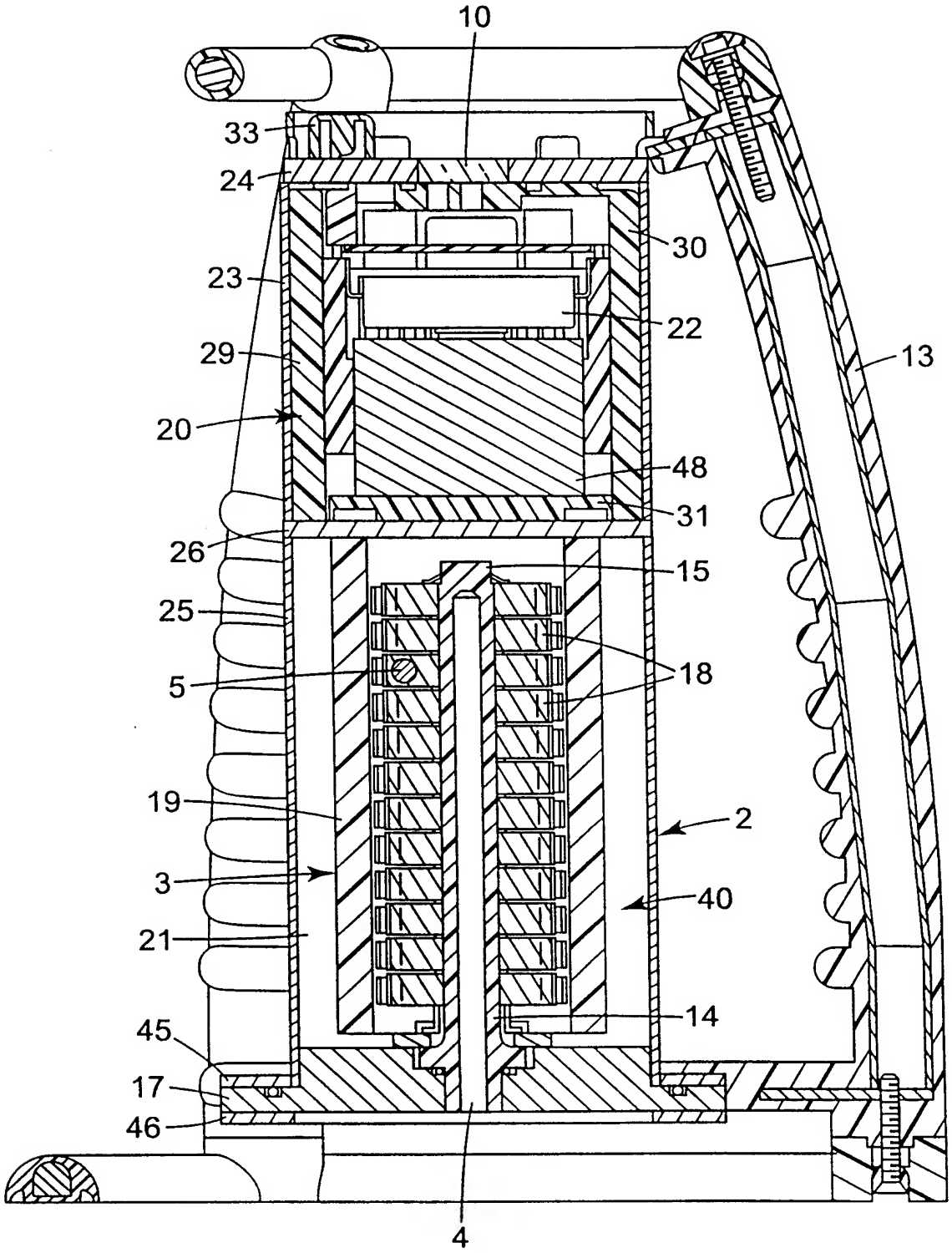


Fig. 3

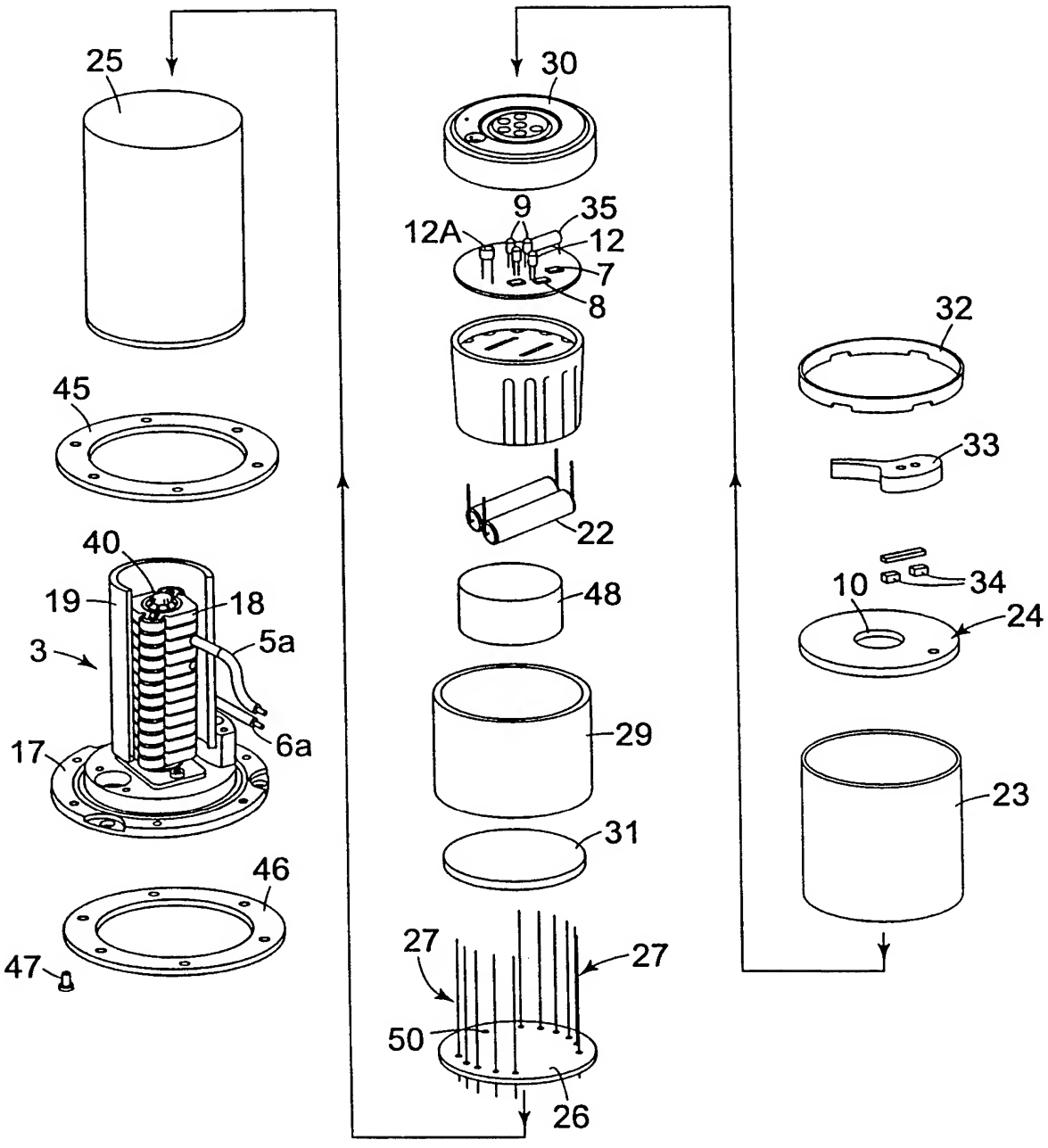

25
45
40
19
18
3
5a
6a
17
46
47
30
9
35
12A
12
7
8
22
48
29
31
27
27
50
26
32
33
10
34
24
23

Fig. 4

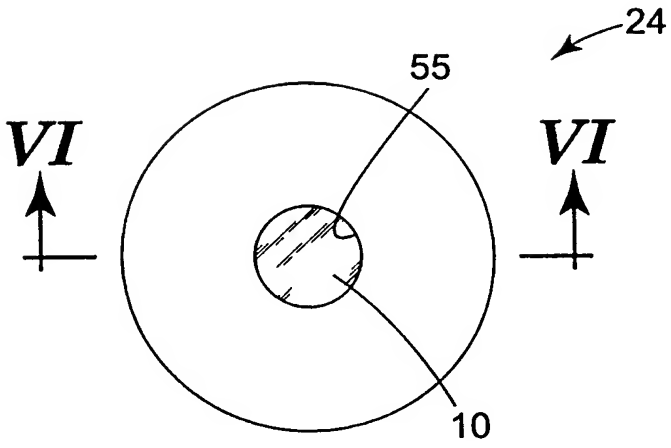


Fig. 5

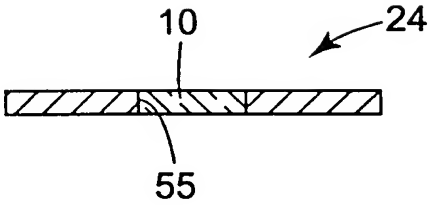


Fig. 6

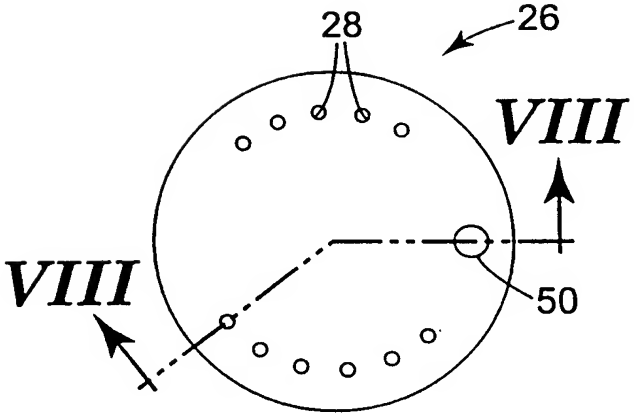


Fig. 7

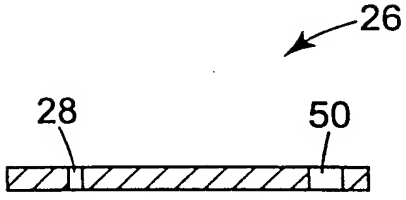


Fig. 8

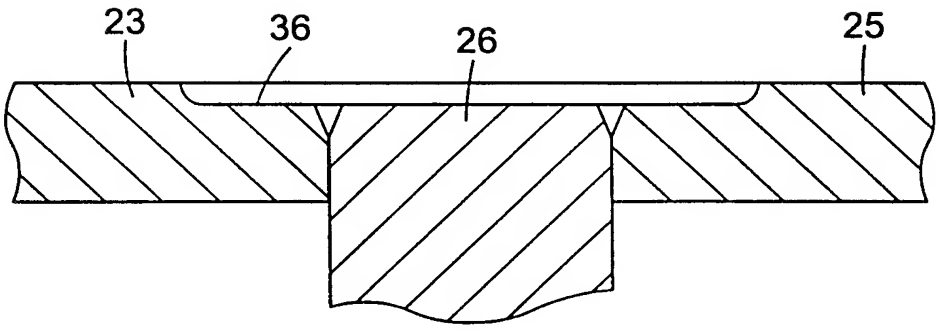


Fig. 9

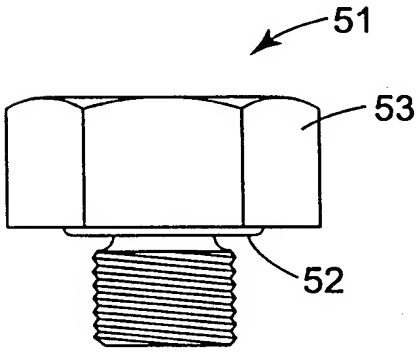


Fig. 10

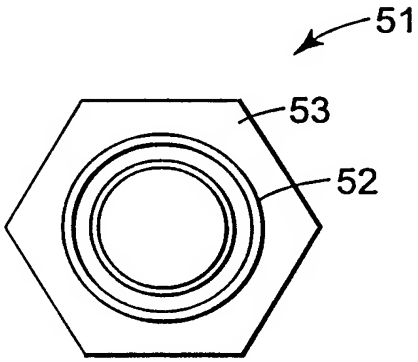


Fig. 11

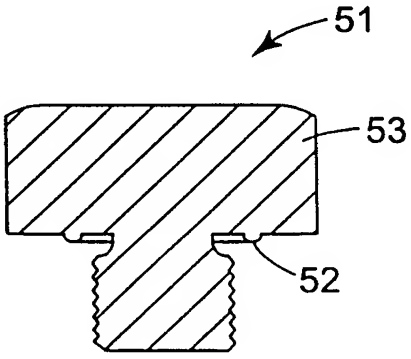


Fig. 12

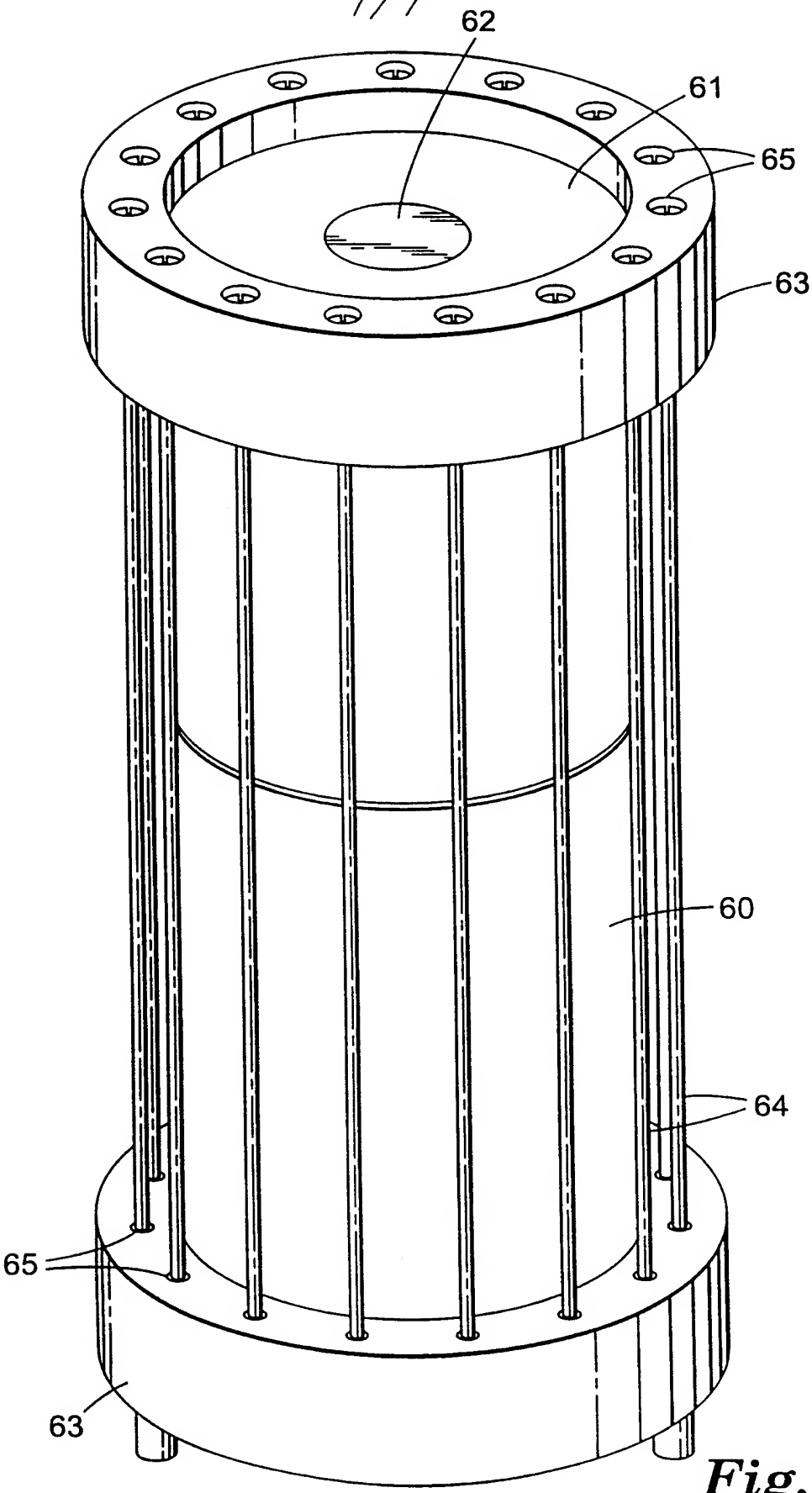


Fig. 13